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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,981	06/24/2003	John D. Roback	050508-1031	2039

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EXAMINER	
CROSS, LATOYA I	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,981	ROBACK ET AL.	
	Examiner	Art Unit	
	LaToya C. Younger	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,8,10-13,15-31,33 and 35-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,8,10-13,15-31,33 and 35-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 21, 2005 has been entered.

Drawings

2. The drawings were received on December 21, 2005. These drawings are acceptable to overcome the drawing objections mentioned in the previous Office Action.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 7, 13, 15-16, 18-22, 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,692,702 to Burshteyn et al.

Burshteyn et al disclose an apparatus for biological sample preparation and analysis, specifically blood cell analysis. The apparatus of Brushteyn et al comprises sample filter vessel (24). The filter vessel comprises a microporous hollow fiber membrane having a plurality of pores. The porous filter allows the vessel to have an irregular bottom. The porous membrane may be a nylon membrane, having a pore size of 0.1-5 microns, as recited in claims 6 and 7 (col. 7, lines 43-59). At col. 15, lines 55-59, Burshteyn et al

disclose that a vacuum forces causes components of the blood to pass through the filter while retaining cells of interest, as recited in claim 16. A fluorescently-labeled antibody (reagent) is added to the blood sample to form a test mixtures, as recited in claims 15 and 19-22. The test mixture is analyzed with a flow cytometer to quantitatively measure the amount of antigen-specific antibody associated with each cell in the test sample as recited in claims 9, 13, 14 (col. 16, lines 44-52).

Burshteyn et al differ from the instantly claimed invention in that there is no disclosure of the flow cytometer being in close proximity to the sample separation system.

At col. 16, lines 23-37, Burshteyn et al disclose the process of filtering and quantifying cell samples. Burshteyn et al disclose that after the blood sample is filtered and the cells are recovered from the filter, the quantifying and differentiating the cell populations takes place using an analyzer, such as a flow cytometer. Thus, it would have been obvious to one of ordinary skill in the art to have the flow cytometer to be in close proximity to the location where the cells are recovered from filtration to make sure that the process of recovering the cells and analyzing the cells flows simply and easily. By having the analysis system in close proximity to the filtration system, less travel of the sample is required and a more efficient system is provided.

5. Claims 1-3, 5, 8, 10-12, 15, 17-31, 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US patent 5,308,990 to Takahashi et al and US Patent 6,008,040 to Datar.

Yaremko et al disclose an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500), pipette assembly (400), washer (406, 410) and imaging system (606), as recited in claims 1-3, 5. The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers, (col. 5, lines 39-42). The containers/receptacles are microcolumns having a filter through which the assay sample travels.

The filters provide an irregular "bottom" for the vessel, as recited in claim 1. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample, as recited in claims 3, 8, 11 and 12 (col. 13, line 61 – col. 15, line 3). At col. 14, line 61 to col. 15, line 3, the reference discloses centrifuging at a lower speed to push the cells toward the filter and to increase cell to cell contact to achieve maximum reactivity, as recited in claims 24-26, 35, 36 and 38. The imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claim 4 (col. 15, line 48 – col. 16, line 21). The pipette assembly comprises a pipette (402) and a robot arm (404), as recited in claim 5 (col. 13, lines 1-12). Yaremko et al disclose that the system is used for analyzing blood samples and for identifying antibodies and antigens as recited in claim 10. With respect to the method of claims 23, 28 and 29, Yaremko et al disclose providing a filter vessel; adding a blood sample and reagent to the vessel, centrifuging the vessel and analyzing the centrifuged components. With respect to claim 31, Yaremko et al disclose that the filter in the microcolumn may be a porous gel material (col. 6, lines 21-32).

Yaremko et al differ from the instant invention in that the reference fails to teach a flow cytometer as the image acquisition system.

Takahashi et al teach that flow cytometers can be used in immunological measurement methods to determine antigen-antibody reactions and agglutination from the antigen-antibody reactions (col. 1,lines 37-53). It would have been obvious to one of ordinary skill in the art to substitute the camera system of Yaremko et al for a flow cytometer to provide a means to determine antigen-antibody interactions and agglutination in immunological assays.

Yaremko et al further differ in that there is no disclosure of the particular filter materials claimed by Applicants.

Datar teaches efficient separation of cells, cellular materials and proteins. Specifically, Datar teaches separation devices such as bead columns. Further, Datar teaches that cellulose acetate beads, polyesters, and nylons are suitable for use in separation columns due to their specific chemistries on their contacting surfaces (col. 4, lines 24-41). It would have been obvious to one of ordinary skill in the art to use filter materials, such as cellulose acetates, polyesters, and nylons as the filter material in the microcolumn of Yaremko et al. These materials are known to be suitable in the separation of cellular material. The ordinarily-skilled artisan would have expected that these filter materials would perform sufficiently in separating blood cells.

Response to Arguments

6. Applicant's arguments filed on December 21, 2005 have been fully considered but they are not persuasive.

With respect to the rejection over Burshteyn et al, Applicants argue that the reference fails to teach that the image acquisition system is in close proximity to the sample separation system. As discussed above, the Examiner notes that the process of Burshteyn et al involves sample separation (filtration) immediately followed by image acquisition (flow cytometry). Thus, one of ordinary skill in the art would have been motivated to have the image acquisition system in close proximity to the sample separation system so that the processing of the sample flows smoothly and at a faster pace since less traveling for the sample is necessary.

With respect to the obviousness rejection over Yaremko in view of Takahashi and Datar, Applicants argue that there is no teaching of polycarbonate track-etched filter materials. In response, the Examiner notes that most of Applicants claimed filter materials (Markusch group of claims 7 and 33) are

taught by Datar. Where Markusch language is used, only one of the grouping need be taught or suggested by the prior art to meet the limitations of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya C. Younger whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 10:30 a.m. - 8:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. T. Cole

MONIQUE T. COLE
PRIMARY EXAMINER

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